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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,608	04/11/2001	Craig Gardner	1023.1117101	1869

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MINNEAPOLIS, MN 55403-2420

EXAMINER

WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/832,608	<b>Applicant(s)</b> GARDNER ET AL.	
	<b>Examiner</b> Eric F Winakur	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-40, 54-90 and 103-113 is/are pending in the application.  
     4a) Of the above claim(s) 69-80, 84, 88-90, 108 and 109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40, 54-68, 81-83, 85-87, 103-107, 110, 111 and 113 is/are rejected.
- 7) ☒ Claim(s) 112 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 - 40, 54 - 68, 81 - 83, and 85 - 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although the claims are directed to an apparatus, they do not recite any positively claimed structural limitations. The claims merely describe optical responses that can be produced by the apparatus. The structure to achieve such a response is not set forth.

### ***Claim Rejections - 35 USC § 102***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claims 1 - 33 and 54 - 59 under 35 U.S.C. 102(e) as being anticipated by Cohenford et al. is hereby maintained.
5. The rejection of claims 34 - 40, 60 - 65, 68, 69, and 81 - 83 under 35 U.S.C. 102(e) as being anticipated by Fellows is hereby maintained.
6. Claims 1, 18, 34, 103 - 107, 110, 111, and 113 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoogenraad et al. Hoogenraad et al. teach calibration of an optical measurement system using Intralipid (scattering solution) and having attenuation to match breast tissue (column 4, line 49 - column 5, line 15). The solution containing the scattering and attenuating materials is contained in a holder

(structure, as claimed). These present two different "optical similarities" and one will necessarily be greater than the other.

### ***Response to Arguments***

7. Applicant's arguments filed 13 October 2004 have been fully considered but they are not persuasive. With regard to the rejections of claims 1 - 33 and 54 - 59 as being anticipated by Cohenford et al., Applicant contends that the processing done by Cohenford et al. will alter the shape of the spectra, and thus Cohenford et al. cannot meet the "similarly shaped spectra" limitation. This is not found persuasive, as the claim does not define "similarly" and while the device of Cohenford et al. may not produce identical spectra, since they are derived from biologically derived samples, they will necessarily have spectra that are similar to the claimed measurement sample. Applicant further argues that an in vivo sample is turbid. However, while this is true for non-invasively obtained measurements, not all in vivo measurements are non-invasive. Thus, the reference sample need not include scattering to meet the claim limitations. Further, Applicant's attention is drawn to the rejection given in paragraph 2 above. For the above reasons, the rejection of claims 1 - 33 and 54 - 59 is hereby maintained.

8. With regard to claims 34 - 40, 60 - 65, 68, 69, 81 - 83 and 85 - 87 as being anticipated by Fellows, it is noted that Applicant has not clearly set forth the structure of these claims (see paragraph 2 above). All reference samples are necessarily a simulation of interaction between a measurement sample and measurement system. Without claiming the particular structure of the device, Fellows is considered to meet these claims.

***Allowable Subject Matter***

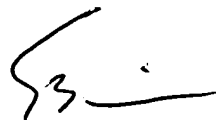
9. Claim 112 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 66 and 67 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571/272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur  
Primary Examiner  
Art Unit 3736